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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,290	07/18/2003	Ronit Yahalomi	1662/611053	4123

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EXAMINER	
OH, TAYLOR V	
ART UNIT	**PAPER NUMBER**
1625	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,290	YAHALOMI ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-30,40-50 and 52* is/are withdrawn from consideration.

5)☒ Claim(s) *31,32 and 34-39* is/are allowed.

6)☒ Claim(s) *33,51,54 and 55* is/are rejected.

7)☒ Claim(s) *53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-55 are pending.

Claims 33, 51, and 54-55 are rejected.

Claims 1-30,40-50, and 52 are withdrawn from consideration.

Claims 31-32, and 34-39 are allowable.

Claim 53 is objected.

Claim Rejections - 35 USC § 112

1. Applicants' argument filed 02/06/07 have been fully considered but are not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 33 under 35 U.S.C. 112, second paragraph, has been maintained due to applicants' failure to modify the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of Claims 51, and 54-55 under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al (U.S. 5,488,150) has been maintained.

2. The rejection of Claims 31-36 and 53 under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al (U.S. 5,488,150) has been withdrawn due to applicants' convincing argument; however, the rejection of Claims 51, and 54-55 under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al (U.S. 5,488,150) has been maintained with reasons of record on 8/04/06 .

The rejection of Claims 51, and 54-55 under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al (U.S. 5,488,150) in view of Grant & Hackh's Chemical Dictionary (fifth ed., page 396, 1987)has been maintained.

3. The rejection of Claims 31-39 and 53 under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al (U.S. 5,488,150) has been withdrawn due to applicants' convincing argument; however, the rejection of Claims 51, and 54-55 under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al (U.S. 5,488,150) in view of Grant & Hackh's Chemical Dictionary (fifth ed., page 396, 1987) has been maintained with reasons of record on 8/04/06 .

Applicants' Argument

Applicants argue the following issues:

a. The term " substantially" is definite and appropriate here because a curve based on data point is inherently inevitably variable to some degree of experimental error; therefore, the expression is proper;

b. Form Epsilon is not detectable in the powder obtained for Form B and H in Sumikawa; the claimed Form Epsilon and the process for its preparation are not obvious in view of the prior art due to the unpredictable nature of polymorphism and the lack of teaching in Sumikawa for preparation of Form Epsilon.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first argument , the Examiner has noted applicants' arguments. However, for the current application, with respect to the terms " substantially depicted in Figure 25 ", it can be used by the subjective decision of the skilled artisan in the art. In Fig 25 , " the pattern" in the phrase of the x-ray diffraction pattern is the identification, which is determined by the pattern of how many peaks are present in the figure; however, in reality, by using the term " substantially", the inventor tries to cover any peaks of the pattern not present in the typical x-ray diffraction figure; the term "**substantially"** of the phrase "depicted in Figure 25 " represents the claimed product to be unknown. In addition, the term "substantially" does imply that what the pattern represented in Fig 25 can be almost true expressions of the crystalline form, but may not be in 100 % representation of the true pattern.

Furthermore, the specification does not elaborate what is meant by the term "substantially" in the specification. Moreover, according to the text book of "Polymorphism in Pharmaceutical Solids" by Harry G. Brittain, it shows clear guidance as to how the identity of the X-ray diffraction can be established in the following :

"The USP general chapter on x-ray diffraction states that identity is established if the scattering angles of the ten strongest reflections obtained for an analyte agree to within +- 0.20 degrees with that of the reference material, and if the relative intensities of these reflections do not vary by more than 20 percent" (see page 236, lines 17-22).

From this teaching and guidance , it follows that there is no need to use the term " substantially" in order to define what applicants' claim may constitute.

In order for the application to be patentable, there should not be any ambiguity or doubts about what the true boundary of the claimed invention may cover for the current invention. Therefore, applicant 's argument is irrelevant to this respect.

Second, regarding the second argument , the Examiner has noted applicants' arguments. However, the claims 51, and 54-55 are directed to a crystalline form of nateglinide containing acetone and acetonitrile unlike the claimed Form Epsilon with the specific X-ray diffraction data.

Furthermore, Sumikawa et al discloses the stable crystals of N-(trans-4-isoproylcyclohexylcarbonyl)-D-phenylalanine compound obtained from the example A1 in the followings:

> 20 ml of an acetone solution of 5 g of N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine were added dropwise to a stirred mixture of acetone (40 ml) and water (60 ml) at 25° C. After cooling to 10° C., the precipitated crystals were filtered and dried at 90° C. at reduced pressure overnight. 4.5 g of dry crystals were obtained. The crystals had a melting point of 138° to 141° C. The powder X-ray diffraction pattern and the infra-red absorption spectrum were measured and the crystals were thus identified as H-type.

(see col. 6 ,lines 43-51).

> The solid N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine suspended in suitable solvent may be of any type, such as amorphous, or in the form of B-type crystals and may be a solvate, e.g. hydrate, methanolate, ethanolate, isopropanolate or acetonitrilate. The amorphous powder may be derived by drying a solvate. Preferably, the suspension is maintained at a temperature of at least 10° C. for sufficiently long that the product crystals contain enhanced amounts of H-type crystals relative to the starting N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine.

(see col. 5 ,lines 10-19).

> Solvents suitable for use in this embodiment of the invention include water, esters such as methyl acetate and ethyl acetate, as well as toluene. Good solvents in which N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine is more readily soluble for example in amounts of at least 1% by weight at 30° C., such as lower alcohols e.g. methanol, ethanol and isopropanol, as well as acetone, acetonitrile, tetrahydrofuran and dioxane may also be used

(see col. 5 ,lines 43-51).

In addition, the prior art expressly teaches that the method for treating a human to depress its glucose level by using the stable crystals of N-(trans-4-isoproylcyclohexylcarbonyl)-D-phenylalanine compound as well as its pharmaceutical composition (see col. 6 ,lines 6-23).

Therefore, applicant 's argument is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor Victor OH, MSD,LAC
Primary Examiner
Art Unit:1625

*** 4/26/07